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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/056,217 | 01/25/2002 | John F. Wironen | RTI-139R | 6903 |

29847 7590 01/27/2004

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EXAMINER

BENNETT, RACHEL M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,217

Applicant(s)

WIRONEN, JOHN F.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/12/02.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1615

DETAILED ACTION

The examiner acknowledges receipt of the Information Disclosure Statement filed 12/9/02.

Specification

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (WO 99/19003) and further in view of Edwards et al. (US 6547866).

Applicants claim an injectable bone-like implant capable of increasing its porosity in situ comprising at least one bone-like compound and a hydrophobic carrier.

Armstrong et al. disclose a composition which comprises a polymer or polymer solution that forms a gel under controlled parameters and a ceramic matrix. The composition may be injected at a trauma site, such as a fracture and shaped to fill any voids present forming and in situ splint and scaffold for the growth of new bone. See abstract. The composite may also serve

Art Unit: 1615

as a controlled release device for a therapeutic agent such as a bone growth factor, an antibiotic, a chemotherapy drug, or a cytokine. The composites may include bone morphogenic proteins or other osteoconductive agents. Preferably the composites are formed in such a manner that the final solid implant is porous with macroscopic pores. See pages 5 and 6. The polymer or polymer solution is selected from the group consisting of resorbable polymers, non-resorbable polymers, natural polymers, synthetic polymers and the aqueous or non-aqueous solutions thereof and combinations thereof. See claims. While Armstrong discloses the composition to be formed in such a manner that the final solid implant is porous with macroscopic pores, Armstrong does not specifically disclose pore forming agents.

Edwards et al. discloses a method of preparing a porous cement composition comprising mixing a powder comprising a calcium source, a phosphate source and a base with a liquid comprising an aqueous solution containing an acid wherein the calcium source and the phosphate source mix with the liquid component to form hydroxyapatite and the acid and base react to form carbon dioxide producing an interconnected porosity in the material. In the preferred embodiment, the base is a carbonate selected from the group consisting of sodium carbonate, sodium bicarbonate, calcium carbonate and calcium bicarbonate or combination thereof. The preferred acid is selected from the group consisting of citric acid, malic acid, fumaric acid lactic acid, succinic acid and orthorhosphoric acid or a combination thereof. See col. 2.

It is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition taught by Armstrong by adding pore forming agents such as sodium bicarbonate and calcium bicarbonate along with

Art Unit: 1615

citric acid as taught by Edwards because of the expectation of forming an interconnected porosity of sufficient pore size as taught by Edwards.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779 (as of 2/4/04, (571) 272-0589). The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927 (as of 2/4/04, (571) 272-0602). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

rmb

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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